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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/523,455	ENGEL ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-9 and 16-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-9 and 16-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 25, 2007, has been entered.

Claims 1, 4-9 and 16-25 are pending in the application and are being examined on the merits herein.

The rejections of the claims under 35 U.S.C. 112, first paragraph, as adding new matter are being withdrawn in view of Applicants' amendments to the claims. Similarly, the rejection of the claims under 35 U.S.C. 112, second paragraph, is being withdrawn in view of the claim amendments.

Applicants' arguments regarding the rejections of the claims over the prior art have been fully considered but are not found persuasive. The claims are rejected as follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-5, 7, 16, 18, 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i) the article by Felberbaum et al. (or record) or Albano et al. (of record) or Engel et al (of record) or the article entitled "The Single or Dual Administration of the Gonadotropin-releasing Hormone Antagonist Cetrorelix in an In Vitro Fertilization-Embryo Transfer Program" by Olivennes et al, 1994, in view of (ii) the article entitled "Synchronization of Endogenous and Exogenous FSH Stimuli in Controlled Ovarian Hyperstimulation (COH)" by Ziegler et al, 1998, and further in view of (iii) the article entitled "Variable Tolerance of the Developing Follicle and Corpus Luteum to Gonadotropin-Releasing Hormone Antagonist-Induced Gonadotropin Withdrawal in the Human" by Hall et al.

Felberbaum et al. teaches that GnRH antagonists such as Cetrorelix and Ganirelix can be administered in an IVF program to avoid premature LH-surges (see summary, in particular.) Felberbaum et al. teaches that patients are treated with HMG starting on day 2 (see summary, in particular), and thus teaches stimulation of ovarian

follicle growth as in part (b). Felberbaum et al. teaches that the patients are administered cetrorelix from day 7 until induction of ovulation with HCG, and thus teaches suppression of premature ovulation by administering the LHRH-antagonist during the follicular cycle as in part (c), and induction of ovulation with HCG as in part (d) (see summary, in particular.) Felberbaum et al. also teaches performing IVF, as in part (e), and also as in claim 25 (see summary in particular.) Thus, Felberbaum et al. teaches a method for therapeutic management of infertility having steps (b)-(e) as recited in claim 1.

Albano et al. teaches a method for assisted reproduction in which an ovarian stimulation protocol is used (see abstract, in particular.) Albano teaches that the ovarian stimulation method involved administration of HMG during day 2 of the menstrual cycle and administration of the gonadotrophin-releasing hormone antagonist cetrorelix (LHRH antagonist) on day 6 of the menstrual cycle (follicular phase) (see abstract, in particular), and thus teaches steps (b) and (c) of the method. Albano et al. further teaches that ovulation is induced with HCG (see abstract, in particular), and thus teaches step (d). Albano et al. teaches the steps can be performed in a method of in-vitro fertilization (see introduction, in particular), and thus teaches step (e) and claim 25. Thus, Albano et al. teaches a method for therapeutic management of infertility having steps (b)-(e) as recited in claim 1.

Engel et al. teaches the treatment of fertility disorders by administering HMG to hyperstimulate the ovaries (see column 1, lines 10-25, in particular), as in step (b) administering an LHRH antagonist such as cetrorelix during the follicular phase, to reduce premature LH surges during stimulated cycles (see column 2, lines 1-15, in particular), as in step (c), and inducing ovulation with HCG (see column 1, lines 55-60, in particular), as in step (d). Engel et al. teaches that the method can be used in an assisted reproduction technique (see column 3, lines 15-40, in particular.) Thus, Engel et al. teaches a method for therapeutic management of infertility having steps (b)-(e) as recited in claim 1.

Olivennes et al. teaches providing a GnRH antagonist such as cetrorelix to prevent premature LH surges in an IVF-ET program (see abstract, in particular.) Olivennes et al. teaches that controlled ovarian hyperstimulation (COH) is carried out with hMG on day 2 of the menstrual cycle, with cetrorelix being administered during the hyperstimulation (follicular phase) (see abstract, in particular.) Olivennes et al. teaches that ovulation is triggered by administration of HCG (see paragraph bridging pages 469-470, in particular.) Thus, Olivennes et al. teaches a method for therapeutic management of infertility having steps (b)-(e) as recited in claim 1.

The references do not specifically teach programming the start of controlled ovarian stimulation by administration of a compound comprising a LHRH antagonist, a progestogen only preparation, a combined oral contraceptive preparation or a

combination thereof, wherein the LHRH-antagonist is administered during the luteal phase and the progestogen only preparation or combined oral contraceptive preparation are administered starting during the luteal phase or day 1 or day 2 of the menstrual cycle.

Ziegler et al. teaches the desirability of permitted advanced timing of the onset of controlled ovarian hyperstimulation (COH) (see page 561, right hand column, in particular.) Ziegler et al. teaches that it is difficult to properly time the onset of HMG administration (see introduction, in particular.) Ziegler et al. teaches that treatments were devised to improve scheduling of treatments for patients and team members by synchronizing FSH rises that initiate new menstrual cycles with the onset of HMG administration for COH (see page 563, left hand column, in particular.) Ziegler et al. teaches that oestradiol was used for timing the follicular phase increase in FSH to provide for the onset of HMG treatment (see discussion, first full paragraph, in particular), and further teaches that advanced programming of COH has been previously achieved with oral contraceptives (see paragraph bridging pages 563-564, in particular.) Ziegler et al. teaches that the oestradiol treatment was started 7.1 days before the onset of menses (luteal phase) and continued for 5 days thereafter (see results section, in particular.) Thus, Ziegler et al. teaches the desirability of permitting the advanced timing of COH treatments by starting the administration of a composition during the luteal phase to allow for advanced scheduling of treatments.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide advanced timing as taught by Ziegler et al. with the assisted reproductive techniques involving administration of HMG and ovarian stimulation such as COH of Felberbaum et al, Albano et al, Engel et al. and Olivennes et al, because the references teach assisted reproductive techniques involving stimulation with HMG prior to induction of ovulation with HCG, whereas Ziegler et al. teaches that a COH treatment involving HMG ovarian stimulation can be improved by providing advanced timing via administration of a composition to allow for improved scheduling of treatments. Thus, one of ordinary skill in the art would have found it obvious to combine the advanced timing method with the assisted reproductive techniques of Felberbaum et al, Albano et al, Engel et al. and Olivennes et al with the expectation of improving the efficiency of treatment scheduling and thus fertilization success with the advanced timing method.

Felberbaum et al, Albano et al, Engel et al, Olivennes et al. and Ziegler et al. do not specifically teach providing advanced timing by administration of a compound comprising a LHRH antagonist, a progestogen only preparation, a combined oral contraceptive preparation or a combination thereof.

The article by Hall et al. teaches that administration of a GnRH antagonist (LHRH antagonist) in the midluteal phase results in luteolysis (see abstract, in particular.) Hall et al. teaches that three daily antagonist injections begun on day 4 or 5 after ovulation

(luteal phase) resulted in menstrual bleeding within 24-48 hrs of the final day of the antagonist administration (see page 997, MLP studies, left hand paragraph, in particular.) Hall et al. teaches that seventy two hours of gonadotropin deprivation (due to GnRH antagonist administration) in the luteal phase resulted in prompt luteolysis in all subjects (see page 998, final paragraph, in particular.) Hall et al. further teaches that in human studies, complete luteolysis is demonstrated in response to GNRH antagonism (see page 999, left hand column first full paragraph, in particular.) Thus, Hall et al. teaches that administration of a GnRH antagonist during the luteal phase results in luteolysis and shortening of the luteal phase. Regarding the specific amount of antagonist administered Hall teaches administering 150 micrograms/kg (see abstract, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of antagonist provided in the method, according to the guidance provided by Hall et al, to provide the desired rate and extent of luteolysis. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Hall et al. does not specifically teach providing an LHRH antagonist that is selected from the group of cetrorelix, teverelix, ganirelix, antide and abavelix. However, as discussed above, Felberbaum et al, Albano et al, Engel et al. and Olivennes et al. teach that cetrorelix is a GnRH antagonists (LHRH antagonist) suitable for

administration. Accordingly, it would have been obvious to provide cetrorelix as the GnRH antagonist in the method of Hall et al. with the expectation of providing a suitable GnRh antagonist.

Accordingly, one of ordinary skill in the art would have found it obvious to provide the GnRH antagonist (LHRH antagonist) of Hall et al. in the advanced timing method of assisted reproductive techniques of Felberbaum et al, Albano et al, Engel et al, Olivennes et al. and Ziegler et al, because Ziegler et al. teaches the desirability of providing controlled timing to allow for better scheduling of procedures and thus better effectiveness of the procedures, such as by controlling the menstrual cycle via oral contraceptives, whereas Hall et al. teaches compositions that control the length and duration of the menstrual cycle, to increase the rate of luteolysis and decrease the duration of the luteal phase. Thus, one of ordinary skill in the art would have found it obvious to provide the composition Hall et al, in the method of Felberbaum et al, Albano et al, Engel et al, Olivennes et al. and Ziegler et al, with the expectation of providing control of the menstrual phases to provide advanced timing for the assisted reproductive techniques. Thus claim 1 is obvious over the recited references.

It is respectfully pointed out that the recitation that the method is for "increasing the quality of fertilized oocytes and embryos" to "optimize oocyte harvesting and fertilization", as recited in claim 1 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable

weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *in re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152 88 USPQ 478, 481 (CCPA 1951.)

Regarding claim 4, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the days on which the compositions are provided, according to the guidance provided by the references, to provide the advanced timing and scheduling of the assisted reproductive techniques. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 5 and 16, the references teach providing cetrorelix as the antagonist during the luteal phase as well as during ovarian stimulation, as discussed above. Regarding claims 7 and 18, Felberbaum et al. teaches administration of ganirelix as a GnRH antagonist, as discussed above. Regarding claim 21, the references teach ovarian stimulation with HMG, as discussed above.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i) the article by Felberbaum et al. (or record) or Albano et al. (of record) or Engel et al (of

record) or the article entitled "The Single or Dual Administration of the Gonadotropin-releasing Hormone Antagonist Cetrorelix in an In Vitro Fertilization-Embryo Transfer Program" by Olivennes et al, 1994, in view of (ii) the article entitled "Synchronization of Endogenous and Exogenous FSH Stimuli in Controlled Ovarian Hyperstimulation (COH)" by Ziegler et al, 1998, and further in view of (iii) the article entitled "Variable Tolerance of the Developing Follicle and Corpus Luteum to Gonadotropin-Releasing Hormone Antagonist-Induced Gonadotropin Withdrawal in the Human" by Hall et al, as applied to claims 1, 4-5, 7, 16, 18, 21 and 25 above, and further in view of U.S. Patent No. 5,470,847 to Garfield et al (of record).

Felberbaum et al, Albano et al, Engel et al, Olivennes et al, Ziegler et al. and Hall et al. are applied as discussed above, and teach assisted reproductive techniques involving a step of inducing ovulation with HMG (a gonadotropin), as discussed above.

The references do not specifically teach inducing ovulation with the particular compounds that are clomiphene, a combination of antioestrogens and gonadoptropins or a combination of clomiphene with gonadotropins, as in claims 22-24.

Garfield et al. teaches that clomiphene is a non-steroidal antiestrogen that stimulates ovulation by stimulating follicle growth and maturation (see column 3, lines 9-20, in particular.)

Accordingly, it is considered that one of ordinary skill in the art would have found it obvious to incorporate clomiphene into the assisted reproductive techniques as discussed by the references, either alone or in combination with a gonadotropin such as HMG, because Garfield et al. teaches that clomiphene is an antiestrogen that stimulates follicle growth and ovulation, whereas the Felberbaum et al, Albano et al, Engel et al, Olivennes et al. and Hall et al. references teach that HCG (a gonadotropin) is provided to induce ovulation, as discussed above. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the clomiphene with the above-described assisted reproductive techniques using the gonadotropin HCG with the expectation of providing suitable stimulation and induction of ovulation for the assisted reproductive techniques

Claims 6, 8-9, 17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over (i) the article by Felberbaum et al. or Albano et al. or Engel et al. or Olivennes et al, and (ii) Ziegler et al, in view of (iii) Hall et al, as applied to claims 1, 4-5, 7, 16, 18, 21 and 25 above, and further in view of (iv) U.S. Patent No. 5,945,128 to Deghengi et al (of record) or Rabasseda et al (of record.)

Felberbaum et al, Albano et al, Engel et al, Olivennes et al, Ziegler et al. and Hall et al. are applied as discussed above, and teach providing a GnRH antagonist (LHRH antagonist) such as cetrorelix or ganirelix in the therapeutic fertility management

technique as recited in claim 1. The references do not specifically teach providing teverelix, antide or abavelix, as recited in claims 6, 8-9, 17 and 19-20.

Dehgenghi teaches that cetrorelix, teverelix, ganirelix and antide are known to be LHRH antagonists (GnRH antagonists) (see column 2, lines 19-23, in particular.)

Rabasseda et al teaches that LHRH-antagonists (GnRH antagonists) such as cetrorelix, ganirelix and abarelix are known to be useful in the treatment of female infertility (see introduction and Table 1 of page 397, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the antagonists of Deghenghi or Rabasseda et al. in the method of Felberbaum et al, Albano et al, Engel et al, Olivennes et al, Ziegler et al. and Hall et al, with the expectation of providing a suitable GnRH antagonist (LHRH antagonist) in the method. Furthermore, regarding the specific amount of the antagonist provided, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the antagonist provided in the method, according to the guidance provided by the references, to provide the desired advanced timing and/or ovulation control. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-9, 16-21 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,319,192 to Engel et al. in view of the Ziegler et al, Hall et al, Dhegenghi, Rabasseda et al and Kent references as applied above. The instant claims differ from those in the patented case because the patented case only recites providing an LHRH-antagonist with stimulation of ovarian follicle growth, ovulation induction and intrauterine insemination, whereas the instant case further recites a programming step involving the

LHRH antagonist or a progestogen composition. However, the combination of such a programming method with an infertility treatment is obvious over the teachings of Ziegler et al, Hall et al, Dhegenghi, Rabasseda et al and Kent, as discussed for claims 1 and 4-9, 16-21 and 25 in the 103(a) rejection made above. Accordingly, the instant claims are not patentably distinct from those in the patented case.

Response to Arguments

Applicant's arguments regarding the rejections of the claims under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

In particular, Applicants argue that it would not be obvious to perform the claimed method because the prior art does not teach or suggest combining COS and ART with a programming of the menstrual cycle. Applicants argue that the references teaching COS and ART, namely Felberbaum et al, Albano et al, Engel et al and Oliveness et al, do not teach or suggest the desirability of timing the start of the treatment program. The Examiner notes that the Ziegler et al. reference is being used to teach the desirability of controlling the timing of the onset of treatment in order to allow better scheduling of procedures, as has been discussed above. The Examiner notes that, with regards to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Ziegler et al. does not teach the specific method of controlling the timing of the onset of COS and ART treatment. The Examiner notes that the Ziegler et al. reference is being applied for it's teaching of the general desirability of controlling the timing of the techniques, for example by providing contraceptives. Thus, Ziegler et al. provides motivation to those of ordinary skill in the art to provide controlled timing of the treatment cycle in order to allow better scheduling. The Examiner notes that the Hall et al. reference is being applied to teach that the menstrual cycle can be controlled with GnRH antagonists (which shorten the menstrual cycle.)

Applicants further argue that Ziegler et al. teaches away from the instantly claimed method by teaching that their approach provides the advantage of permitting advance timing of the onset of COH treatments "when gonadotrophin-releasing hormone (GnRH) *agonists* are not used" and to control the onset of "natural cycles" (emphasis added) (see page 11 of Remarks submitted on April 25, 2007.) Applicants' assert that this constitutes a teaching away from modifying a normal COS/ART procedure by administering a LHRH antagonist during the preceeding cycle to induce timed onset of menstrual bleeding. The Examiner respectfully disagrees, and notes that Ziegler et al. does not expressly teach away from the use of LHRH antagonists for controlling the onset of COH treatments. Furthermore, as Ziegler et al. generally

teaches the desirability of permitting advanced timing for the onset of COH treatments to allow for better scheduling, it is considered that the reference as a whole teaches the desirability of incorporating agents and methods capable of providing the desired advanced timing.

Applicants also argue that the method of Ziegler et al. does not affect the timing of the onset of menstrual bleeding (see paragraph bridging page 11 of Remarks submitted April 25, 2007.) The Examiner notes that the Ziegler et al. reference teaches controlling the FSH levels for the onset of COH, and teaches that it is known to control the duration of the menstrual cycle in order to provide such programming (See page 563, in particular), and thus it is considered that Ziegler et al. teaches the general desirability of controlling the onset of the menstrual cycle and/or hormones associated with the onset of the menstrual cycle.

Applicants further argue that one of ordinary skill in the art would not have been motivated to provide the LHRH antagonists in the claimed method because they were considered to interfere with mechanisms involved in germinal vesicle breakdown and cell signaling pathway driving the oocyte into meta phase II, and to interfere with other general mechanisms, and Applicants cite a number of references that supposedly show this state of the art (see page 12 of Remarks submitted April 25, 2007.) The Examiner respectfully disagrees with this assertion. The Examiner notes that the Felberbaum et al, Albano et al, Engel et al and Oliveness et al. references all teach GnRH or LHRH

antagonists that are safe and effective for use with assisted reproductive techniques, whereas the Hall et al. reference teaches that GnRH antagonist shorten the luteal phase of the menstrual cycle, thus rendering it obvious to combine with a method such as that in Ziegler to provide timing of menstrual cycles for assisted reproductive techniques.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER